UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	Civil Action No. 01-CV-12257 PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Judge Patti B. Saris Chief Magistrate Judge Marianne B. Bowler

THE BMS DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION FOR RECONSIDERATION OR, IN THE ALTERNATIVE, FOR AN ORDER CERTIFYING THE COURT'S MEMORANDUM AND ORDER OF NOVEMBER 2, 2006, FOR APPEAL PURSUANT TO 28 U.S.C. § 1292(b)

DWYER & COLLORA, LLP
600 Atlantic Avenue
Boston, Massachusetts
(617) 371-1000

Of Counsel:
Thomas E. Dwyer, Jr.

HOGAN & HARTSON L.L.P.
875 Third Avenue
New York, New York 10022
(212) 918-3000

Of Counsel:
Steven M. Edwards, Esq.
Lyndon M. Tretter, Esq.

Attorneys for Defendants Bristol-Myers Squibb Co., Oncology Therapeutics Network Corp. and Apothecon, Inc.

Defendants Bristol-Myers Squibb Co., Oncology Therapeutics Network Corp. and Apothecon, Inc. (the "BMS Defendants") respectfully submit this memorandum in support of their motion for reconsideration or, in the alternative, for an order pursuant to 28 U.S.C. § 1292(b) certifying for appeal this Court's construction of Section 4556(a) of the Balanced Budget Act of 1997[1] ("BBA") in its Memorandum and Order dated November 2, 2006 ("Order").

Preliminary Statement

In March of this year, both sides moved for summary judgment on the claims of Classes 1 and 2. Plaintiffs argued that "average wholesale price" or "AWP" in the BBA instructed Medicare to reimburse providers at the average price at which wholesalers sold defendants' products, inclusive of manufacturer discounts and rebates, and that defendants' alleged publication of prices different from such an average constituted a *per se* deceptive or unfair practice under Massachusetts law. Defendants argued that plaintiffs' interpretation of the BBA was untenable as a matter of statutory construction and that, in any event, plaintiffs could not establish causation under Massachusetts law because it was indisputable that the Health Care Financing Administration ("HCFA") and Congress, who established the Medicare reimbursement amounts, knew the nature and extent of the differences between published AWPs and providers' average acquisition costs for the drugs at issue in this case.

In its Order, the Court denied both motions (except for defendants' motion with respect to Medicare Part B drugs furnished in 2004), but wrote an opinion defining the term "average wholesale price" as it is used in the BBA to mean the average prices that providers pay for drugs, net of manufacturer discounts and rebates. (Order at 23.) It is unclear, to defendants at least, what the impact of the Court's opinion will be on the remaining issues in the case, but

[1] Pub. L. No. 105-33 § 4556(a), 111 Stat. 251, 462 (1997) (codified at 42 U.S.C. § 1395u(o)) (DX 1906, attached hereto at Tab A.) (All citations to "DX __" refer to Defendants' trial exhibits, copies of which are attached hereto.)

plaintiffs continue to contend that it establishes liability as a matter of law. At the same time, it is clear that if defendants' position is correct, it will substantially narrow the issues in the case because plaintiffs cannot prevail unless they can prove deception.

It is also clear that the Court's ruling may have an impact on litigation pending nationwide. While BMS will argue that the Order should have no impact for a variety of reasons, its adversaries will undoubtedly argue that it does. It is difficult to predict how the issue will play out in those proceedings, and waiting until the end of this case to appeal the Court's ruling may cause BMS to suffer irreparable harm.

In its Opinion, the Court noted that it relied heavily on the government's brief as amicus curiae for the statutory and regulatory background. (Order at 3 n. 3.) Among other things, the government argued that the BBA directed the Secretary of Health and Human Services ("HHS") to determine AWPs and did not mandate the adoption of the prices that appeared in industry publications (the "Publications"). The Court agreed and held that Congress did not intend the Secretary to define average wholesale price as the AWPs used by the Publications.

Subsequent to receiving the Court's Order, BMS discovered that the government's brief was based on a recital of the Congressional record that was inaccurate in two material respects. First, the government's position is similar to the Senate version of what became Section 4556(a) of the BBA, but the Senate version was rejected by the full Congress in favor of the House version, which contemplated that AWP would be defined in accordance with its industry usage. Second, the government's position is inconsistent with Section 201 of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 ("BBRA"),[2] which

[2] Pub. L. No. 106-113, App. F - H.R. 3426, 113 Stat. 1501, 1501A-321 (codified at 42 U.S.C. § 1395l(t)), cited excerpts attached hereto at Tab B.)

provided for payments to hospitals for out-patient chemotherapy in certain instances based on the published AWPs.

BMS respectfully moves for reconsideration to bring these matters to the attention of the Court so that the Court can consider whether they affect its opinion. If the Court determines that they do not affect its opinion, then BMS respectfully requests that the Court certify the issue of the proper definition of average wholesale price in the BBA for an interlocutory appeal pursuant to 28 U.S.C. § 1292(b). A resolution of these issues need not and will not affect the ongoing trial.

Standards Governing the Motion

A motion for reconsideration may be granted where the moving party demonstrates that the Court has overlooked or misapprehended a material issue of law or fact. *Colon v. Wyeth Pharm. Co.*, No. Civ. 03-2327, 2006 WL508094, at *2 (D.P.R. March 1, 2006). Here, the Court concluded that, in passing the BBA, Congress directed the Secretary to interpret the term "average wholesale price" in accordance with its plain meaning when, in fact, portions of the legislative history, which the Court did not consider, make clear that Congress intended the Secretary to use the AWPs that appeared in industry publications. In addition, the Court's interpretation is inconsistent with the way Congress used the term average wholesale price in the BBRA.

Under 28 U.S.C. § 1292(b), a district court judge may certify for immediate appeal an otherwise non-appealable order, where that judge:

> [S]hall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation . . . .

There is clearly substantial ground for difference of opinion as to the proper definition of average wholesale price as it appears in the BBA, and a definitive ruling from the Court of Appeals on that question will materially advance the ultimate termination of this litigation.

Argument

I.

THE COURT'S ORDER OVERLOOKS SIGNIFICANT LEGISLATIVE HISTORY IN THE CONGRESSIONAL REPORTS LEADING TO THE BBA AND CONFLICTS WITH THE USE OF AWP IN THE 1999 BBRA

A. The Legislative History of the BBA

The BBA is an amalgamation of a number of legislative proposals, from the President and numerous authorizing committees, each with the goal of balancing the Fiscal Year 2002 Federal budget through fundamental reforms of government entitlements. Operating under the directives given in the House Concurrent Resolution on the Budget for Fiscal Year 1998,[3] each authorizing committee was directed to provide to the House Budget Committee budget reconciliation recommendations with respect to their areas of oversight. As demonstrated below, the Budget Committee compiled these recommendations and reported what became House Bill 2015 to the full House.

President Clinton's budget proposal to Congress for Fiscal Year 1998 included a provision which provided that Medicare's payment for drugs would be based on provider acquisition cost.[4] The House rejected President Clinton's proposal and passed House Bill 2015 on June 25, 1997. That legislation included two provisions dealing with reimbursement for Medicare Part B drugs: Sections 4616 and 10616, recommended by the House Commerce Committee and the House Ways and Means Committee, respectively. Identical in their text,

[3] H.R. Con. Res. 84, 105th Cong. § 105 (1997).

[4] *See President's Fiscal Year 1998 Budget Proposal for Medicare, Medicaid, and Welfare: Hearing Before the S. Comm. on Finance*, 105th Cong. 265 (1997), excerpts attached hereto at Tab C.

Sections 4616 and 10616 specified that in any case where payment is not made on a cost or prospective payment basis, "the amount payable for the drug or biological is equal to 95 percent of the average wholesale price."[5]

It is clear from the Budget Committee Report that accompanied House Bill 2015, House Report 105-149, that when the House bill used the phrase "average wholesale price," it referred to the price in the Publications. For example, notwithstanding the Congressional Budget Office's warning that manufacturers had the ability to affect that reimbursement measure, the Budget Committee report stated:

> Currently, Medicare pays [100% of] the average wholesale price (AWP) for drugs, which is a price reported by the manufacturer. Under the [House] proposal, Medicare would pay 95% of the [same] AWP . . . . Because the provision has no mechanism for controlling inflation in drug prices, CBO assumes that manufacturers would raise the AWP for their products to compensate for the payment cuts. Nevertheless, the provision [for 95% instead of 100%] would save $0.4 billion over five years.[6]

The Budget Committee added that it would "monitor AWPs to ensure that this provision does not simply result in a 5% increase in AWPs."[7] These statements would not make any sense unless the AWPs in the House bill were the AWPs previously used by HCFA, which were the AWPs reported in the Publications.

The Senate also passed its budget bill, Senate Bill 947, on June 25, 1997 and immediately incorporated the language of Senate Bill 947 into House Bill 2015 as an amendment and sent it back to the House.[8] Section 5526 was the companion provision to those of the House bill discussed above. It differed from the House bill in two significant respects. First, the Senate

---

[5] H.R. 2015, 105th Cong. § 4616, § 10616 (as passed by House, June 25, 1997), cited excerpts attached hereto at Tab D.

[6] H.R. REP. NO. 105-149, at 1398 (1997) (emphasis added), cited excerpts attached hereto at Tab E.

[7] *Id.* at 1354.

[8] *See* 143 Cong. Rec. S6144-45 (daily digest Jun. 25, 1997), cited excerpt attached hereto at Tab F.

bill language stated that the reimbursement amount would equal "95 percent of the average wholesale price, as specified by the Secretary."[9] Second, it directed the Secretary to "conduct such studies or surveys as are necessary to determine the average wholesale price (and such other price as the Secretary determines appropriate) of any drug or biological for purposes of paragraph (1)."[10] Thus, the Senate bill was similar to this Court's interpretation of "average wholesale price" as something separate from the prices in the Publications and that could be determined by the Secretary based on surveys of discounts and rebates.

After the Senate sent the amended House Bill 2015 back to the House, a conference was required to iron out the differences between the original and Senate-amended versions of House Bill 2015, and the House provision prevailed. The final provision does not provide for the Secretary to determine the AWP, but rather simply states that drugs should be reimbursed at "95 percent of the average wholesale price."[11] Further, the law provides that the Secretary is only "to study the effect" of the law on the AWPs; the Secretary has no power to conduct studies or surveys to "determine" a price.[12] Again, this clearly shows that the AWPs ultimately adopted in the statute were the *pre-existing* AWPs in the publications -- those were the only available AWPs which the Secretary could use to "study" the new law's "effect."[13]

The Conference Committee Report confirms this. It states that "[t]he conference agreement includes the House bill with modifications."[14] Again, the modifications are embedded

---

[9] H.R. 2015, 105th Cong. § 5526(a)(o)(1) (as amended by Senate, June 25, 1997) (emphasis added), cited excerpts attached hereto at Tab G.
[10] *Id.* at § 5526(a)(o)(4).
[11] BBA, Pub. L. No. 105-33, § 4556(a), 111 Stat. 251, 462 (1997) (codified at 42 U.S.C. § 1395u(o)). (DX 1906, attached hereto at Tab A.)
[12] *Compare* BBA § 4556(c) (emphasis added) (DX 1906, attached hereto at Tab A) *with* H.R. 2015, 105th Cong. § 5526(a)(o)(4) (as amended by Senate, June 25, 1997) (emphasis added), attached hereto at Tab G.
[13] BBA § 4556(c).
[14] H.R. CONF. REP. NO. 105-217, at 798 (1997) (emphasis added), cited excerpts attached hereto at Tab H.

in the subsection directing the Secretary "to study the effect"[15] on the published AWPs of Medicare's reducing reimbursement from 100% to 95% of those AWPs and to report back to the House Ways and Means Committee and the Senate Finance Committee not later than July 1, 1999.

The differences between the House and Senate bills -- specifically the elimination of the Secretary's discretion to determine AWPs based on surveys -- is significant in demonstrating Congress' final intent. Where Congress includes language in an earlier version of a bill but deletes it prior to enactment, it may be presumed that the language was not intended. *Russello v. United States*, 464 U.S. 16, 23 (1983). The legislative history is therefore crystal clear: Congress intended the Secretary to use the AWPs in the Publications.

B. The Use of AWP in The 1999 BBRA

Medicare Part B services can be provided in a hospital out-patient setting, as well as in a physician's office. In the 1997 BBA, Congress instructed HCFA to develop a prospective payment system for hospital out-patient procedures, which ultimately became known as the "OPPS" (Outpatient Prospective Payment System) program.[16] HCFA then set out to establish OPPS and to determine the fee schedule payments, initially through a proposed rule issued on September 8, 1998.[17] Given the content of this rule, however, Congress became concerned that the scheduled amount (the "OPD fee schedule amount") for drugs and biologicals, including chemotherapy, might be too low to ensure patient access to care.

In 1999, Congress passed the BBRA. Section 201(b) of the BBRA provides for transitional "pass-through" payments to be made to outpatient hospitals for, among other things,

[15] BBA § 4556(c) (emphasis added) (DX 1906, attached hereto at Tab A.)
[16] 42 U.S.C. § 1395l(t).
[17] Prospective Payment System for Hospital Outpatient Services, 63 Fed. Reg. 47552 (proposed Sept. 8, 1998) (to be codified at 42 C.F.R. pt. 419).

certain cancer therapy drugs and biologicals. The statute provides that, for a transitional period of 2-3 years, the Secretary shall provide for "an additional payment" over the OPD fee schedule amount for such drugs.[18] That additional payment is tied to Section 4556(a) of the 1997 BBA (Social Security Act § 1842(o), codified at 42 U.S.C. § 1395u(o)) -- the provision providing for reimbursement at 95% of average wholesale price. The legislative history to the BBRA explains why:

> The parties to the agreement are concerned that HCFA's proposed payment system does not adequately address issues pertaining to the treatment of drugs, biologicals and new technology….The [BBRA Section 201] provisions would establish transitional payments to cover the added costs of certain services involving the use of medical devices, drugs and biologicals. Hospitals using these drugs, biologicals and devices would be eligible for additional payments.
>
> * * *
>
> [F]or drugs and biologicals, the amount of the additional payment is the amount by which 95 percent of the Average Wholesale Price (AWP) exceeds the portion of the applicable outpatient fee schedule amount that the Secretary determines is associated with the drug or biological.[19]

HFCA issued its final rule that implemented the pass-through provision on April 7, 2000. In doing so, the agency had to establish the OPD fee schedule amounts for drugs and biologicals to determine the level of the pass-through payment (*i.e.*, the difference between 95% of AWP and that amount). After commissioning a study of hospital acquisition costs, HCFA set the OPD fee schedule amount for drugs and biologicals as 68% of published AWP for single-source drugs; 61% of AWP for multi-

[18] *See* Section 201(b) of the BBRA, Pub. L. No. 106-113, App. F - H.R. 3426, 113 Stat. 1501, 1501A-321 (codified at 42 U.S.C. § 1395l(t)), attached hereto at Tab B.
[19] H.R. CONF. REP. NO. 106-479, at 868-869 (1999) (emphasis added), cited excerpts attached hereto at Tab I.

source drugs and 43% for multi-source drugs with generic competitors.[20] Pursuant to Section 201 of the 1999 BBRA, the Secretary paid hospitals outpatient departments the difference between those OPD fee schedule amounts and 95% of AWP for the pass-through drugs.[21]

Section 201 of the 1999 BBRA and the HCFA OPPS regulations are inconsistent with this Court's interpretation of AWP in Section 4556(a) of the BBA in its Order. If the Court were correct that Congress adopted a "plain meaning" of AWP in 1997, the 1999 BBRA and HCFA OPPS regulations produce anomalous results. The outpatient hospital units would not be entitled to any "additional payments" unless 95% of AWP is greater than the OPD fee schedule, which is based on a lesser percentage of the AWPs published in the Publications. The 1999 BBRA statute and HCFA regulations setting OPD fee schedule amounts make sense only if the AWP in the 1997 BBA statute is interpreted to mean AWP in the Publications.

II.

THE COURT'S ORDER INVOLVES A CONTROLLING QUESTION OF LAW AS TO WHICH THERE IS SUBSTANTIAL GROUND FOR DIFFERENCE OF OPINION AND AN IMMEDIATE APPEAL MAY MATERALLY ADVANCE THE ULTIMATE TERMINATION OF THE LITIGATION

As the Court recognized in its Order, where a statutory or regulatory term is an industry term of art, it should be defined in accordance with its industry usage.

---

[20] Prospective Payment System for Hospital Outpatient Services, 65 Fed. Reg. 18434, 18481 (April 7, 2000) (codified at 42 C.F.R. pt. 419), cited excerpts attached hereto at Tab J.

[21] It is important to note that, under OPPS, drugs that did not qualify for pass-through status, were not reimbursed based on AWP at all. They were reimbursed based on Ambulatory Payment Classifications or APCs that "bundled" the drug and services reimbursement into a fee schedule amount that had nothing to do with published AWPs. Moreover, even for the pass-through drugs, while Medicare adjusted its portion of the payment to the hospital provider based on 95% of published AWP, the beneficiary was obligated to make its co-payment amount based on the fee schedule and not 95% of published AWP. *See* Medicare Program; Changes to the Hospital Outpatient Prospective Payment System for Calendar Year 2002, 66 Fed. Reg. 59856 (Nov. 30, 2001) (codified at 42 C.F.R. pt. 419).

(Order at 16.) The Court concluded, however, that the term "average wholesale price" did not have a settled meaning in the industry until 2003. (*Id.* at 23.) That is inconsistent with the clear and unambiguous record before the Court.

As early as 1969, the Department of Health, Education and Welfare recognized that AWPs "rarely have any realistic relationship with actual acquisition costs . . . ."[22] In 1974, HCFA noted that AWPs "are frequently in excess of actual acquisition cost to the retail pharmacist."[23] In 1984, the Office of Inspector General ("OIG") of HHS issued a report that stated: "Within the pharmaceutical industry, AWP means non-discounted list price."[24]

In 1988, HCFA again noted that AWPs are essentially "suggested list prices" and that actual selling prices are "less than the suggested list prices."[25] In 1989, OIG quoted an industry participant's comment that "it is recognized in the industry that there are discounts off of AWP . . . selling price is based on AWP less a discount or . . . cost plus a markup."[26] In June 1991, HCFA proposed that drugs be reimbursed under Medicare Part B at 85% of AWP "as published the Red Book and similar price listing," explaining that it was proposing a 15% discount below AWP because "we believe that

---

[22] *Prescription Drugs Under Medicare: The Legacy of the Task Force on Prescription Drugs*, reprinted in 10 JOURNAL OF RESEARCH IN PHARMACEUTICAL ECONOMICS, No. 2/3 (2001) at 148. (Cited excerpts of DX 1653 attached hereto at Tab K.)

[23] Reimbursement of Drug Cost – Medical Assistance Program, 39 Fed. Reg. 41480, 41480 (Nov. 27, 1974). (DX 1850, attached hereto at Tab L.)

[24] OIG, *Changes to the Medicaid Prescription Drug Program Could Save Millions*, at 3 (1984). (DX 1039, attached hereto at Tab M.)

[25] Medicare Program; Payment for Covered Outpatient Drugs, 54 Fed. Reg. 37208, 37214 (proposed Sept. 7, 1989) (to be codified at 42 C.F.R. pt. 414), cited excerpts attached hereto at Tab N.

[26] OIG, *Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program*, at 3 (Oct. 3, 1989). (DX 1044, attached hereto at Tab O.)

the Red Book and other wholesale price guides substantially overstate the true cost of drugs."[27]

In November 1991, when HCFA adopted the final regulation providing for reimbursement at 100% of AWP, it observed that "many drugs could be purchased for considerably less than 85% of AWP -- particularly multi-source drugs . . . ."[28] In November 1992, OIG interviewed representatives of Red Book who "confirmed that the AWP is not designed to reflect physicians' costs."[29] HCFA nevertheless directed its carriers to use the Publications to determine AWPs.[30]

As noted above, Congress explicitly rejected the Administration's proposal that reimbursement be based on "actual acquisition cost" when it adopted 95% of AWP in the BBA.[31] HCFA then directed its carriers to carry out the Act by using the AWPs in the Publications, commenting that AWP "does not reflect the cost to the physician or supplier furnishing the drug to the Medicare beneficiary."[32] Shortly after Congress passed the BBA, OIG stated that "[t]he AWP is determined through *the Red Book* or similar pricing publications" and observed that "[h]istorically, carriers have

---

[27] Medicare Program; Fee Schedule for Physicians' Services, 56 Fed. Reg. 25792, 29800 (proposed June 5, 1991) (to be codified at 42 CFR pt. 405). (DX 1855, attached hereto at Tab P.)

[28] Medicare Program; Fee Schedule for Physicians' Services, 56 Fed. Reg. 59502, 59524 (Nov. 25, 1991) (codified at 42 C.F.R. pts. 405, 413 and 415). (DX 1189, attached hereto at Tab Q.)

[29] OIG, *Physicians' Costs for Chemotherapy Drugs*, at 5 (Nov. 6, 1992). (DX 1053, attached hereto at Tab R.)

[30] Memorandum from Charles R. Booth to All Associate Regional Administrators for Medicare, at 2 (March 15, 1994). (DX 1055, attached hereto at Tab S.)

[31] Medicare and Medicaid Beneficiary Protection Act of 1997, H.R. 2632, 105th Cong. § 206 (1997), attached hereto at Tab T; Balanced Budget Act of 1997, Pub. L. 105-33 § 4556(a) (1997) (codified at 42 U.S.C. § 1395u(o)), attached hereto at Tab A.

[32] HCFA, *Implementation of the New Payment Limit for Drugs and Biologicals*, Program Memorandum No. AB-97-25, at 1 (Jan. 1998). (DX 1076, attached hereto at Tab U.)

utilized AWP and not estimated acquisition cost to develop Medicare reimbursement for prescription drugs."[33]

In 2000, when the Secretary attempted to redefine AWP to reflect acquisition cost, Senators Bond and Ashcroft objected, telling the Secretary that "in the Balanced Budget Act of 1997 (BBA), Congress instructed HHS to base Medicare reimbursement for cancer drugs on 95 percent of the 'average wholesale price' or AWP, a term widely understood and indeed defined by HHS manuals to reference amounts reflected in specified publications."[34] Senator Abraham reminded the Secretary that "Congress laid down very clear legislation regarding these [drug] reimbursements in the Balanced Budget Act of 1997, where it instructed HCFA to base these reimbursement rates at 95% of the average wholesale price (assumed to be an industry-accepted AWP, not one derived by government bureaucrats . . . .)"[35] The Secretary then withdrew this program and reverted to using the Publications to determine AWPs, explaining that "congressional action may preclude the use of this alternative source."[36]

As noted by the Court's own expert, Dr. Berndt, throughout this entire time period, the industry understood that the term "average wholesale price" referred to the AWPs in the Publications, and the AWPs in the Publications represented a mark-up

---

[33] OIG, *Excessive Medicare Payments for Prescription Drugs*, at 1 (Dec. 1997). (DX 1075, attached hereto at Tab V.)

[34] Letter from Christopher S. Bond and John Ashcroft to Donna E. Shalala, Secretary, DHHS, at 1 (Aug. 3, 2000) (DX 1087, attached hereto at Tab W.)

[35] Letter from Senator Spencer Abraham to Donna E. Shalala, Secretary, DHHS, at 2 (Sept. 6, 2000). (DX 1089, attached hereto at Tab X.)

[36] HCFA, *Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program*, Program Memorandum No. AB-00-115, at 1 (Nov. 17, 2000). (DX 1093, attached hereto at Tab Y.)

of 20% to 25% over wholesale acquisition cost or "WAC."[37] Furthermore, the entire industry, as well as the federal government and Congress, recognized that AWP was not acquisition cost.[38] Given this record, we respectfully suggest that there is no basis for the Court to define AWP in a manner that is inconsistent with the industry understanding and in a way that no industry participant would have reasonably understood.

In its Order, the Court noted that "[w]hile there is some evidence [that AWP had an established and settled meaning in the industry prior to 2003], there is also evidence to the contrary." (Order at 18.) We respectfully submit that there is no evidence that any manufacturer believed that AWP represented acquisition cost, and there is overwhelming evidence that most payors, especially HCFA, understood that it did not. Moreover, it was undisputed that Congress understood that AWP did not represent acquisition cost.

Even if the court is inclined to credit the claim of some payors that they were confused about the meaning of AWP, "a dispute about a statute's or regulation's proper construction cannot be resolved simply by placing the gloss of 'plain meaning' on one competing interpretation." *Commonwealth of Mass. v. Blackstone Valley Elec. Co.*, 67 F.3d 981, 986 (1st Cir. 1995). Under those circumstances, the Court should have found the statute ambiguous and considered extrinsic evidence of Congress's intent, including the legislative history recited above. *General Motors Corp. v. Darling's*, 444

[37] IMS, *Pharma Pricing USA* at 103-05 (1995) (cited excerpts attached hereto at Tab Z); Report of Independent Expert Ernst R. Berndt to Judge Patti B. Saris dated Feb. 9, 2005 ("Berndt Report") ¶¶ 20-22 (cited excerpts attached hereto at Tab AA).

[38] Plaintiffs' expert Dr. Rosenthal has testified that the industry understood that AWP was not acquisition cost. (*See* Nov. 15, 2006 Trial Transcript of *In re Pharmaceutical Average Wholesale Price Litig.*, CA No. 01-12257-PBS, MDL No. 1456, at 92-94.)

F.3d 98, 108 (1st Cir. 2006). The Court should also have permitted defendants to supplement the record if there was any uncertainty about the industry's understanding.

In its Order, the Court expressed concern that defendants were arguing that "average wholesale price" should be construed "to mean a retail sticker price without any connection to prices in the market . . . ." (Order at 20.) As BMS has demonstrated, however, the AWPs for its drugs are "connected" to the market because they are related to its list prices, and BMS has substantial sales at or near list prices. Defining average wholesale price as the AWPs that appear in industry publications would not amount to surrendering control to a metric that is wholly dictated by the pharmaceutical industry any more than basing reimbursement on acquisition cost would.

The question of statutory interpretation should not be confused with the question of deception. Defining average wholesale price as a price that appeared in industry publications still leaves open the question whether any payor was deceived. [39] Statutory definition should not be used as a short-cut to avoid that question or, even more problematic, impose liability where no payor was deceived.[40]

We understand that the Court disagrees with this analysis, but we respectfully suggest that, at the very least, there is substantial ground for difference of opinion on this issue and it is novel and important. The First Circuit has granted interlocutory appeals where it has found the issue "to be sufficiently novel and important,

[39] In this regard, BMS notes that it agrees with the Track 2 defendants that the Court could rule on plaintiffs' claim without reaching the ultimate question of the correct statutory definition of AWP.

[40] While a violation of a statute does not necessarily constitute unfairness, absent a violation of a statute, a plaintiff cannot succeed under either the deception or unfairness prong of Mass. Gen. L. ch. 93A where no one has been deceived. *Brazas Sporting Arms, Inc. v. American Empire Surplus Lines Ins. Co.*, 220 F.3d 1, 9 (1st Cir. 2000); *Tagliente v. Himmer*, 949 F.2d 1,7 (1st Cir. 1991); *Mass. Farm Bureau Fed'n v. Blue Cross of Mass., Inc.*, 532 N.E.2d 660, 665 (Mass. 1989); *Madan v. Royal Indem. Co.*, 532 N.E.2d 1214, 1218 (Suffolk Co. 1988); *Dinjian v. Dinjian*, 495 N.E.2d 882, 888 (Middlesex Co. 1986).

and the circumstances sufficiently out of the ordinary, as to fulfill the statutory requisites." *In re San Juan Dupont Plaza Hotel Fire Litig.*, 859 F.2d 1007, 1010, n.1 (1st Cir. 1988). Courts in this circuit have also certified interlocutory orders where a case and other cases would benefit from prompt resolution of an important question. *See Natale v. Pfizer Inc.*, 379 F. Supp. 2d. 161, 181-82 (D. Mass. 2005); *Miara v. First Allamerica Fin. Life Ins. Co.*, 379 F. Supp. 2d 20, 67-68 and n. 53 (D. Mass. 2005).

BMS is not suggesting that the ongoing trial be delayed to permit this interlocutory appeal. The court has previously indicated that it is unlikely to rule until February at the earliest. An expedited appeal to the First Circuit will give the Court the benefit of the Court's view before it rules, and will guide the Court in formulating jury instructions for the Class 1 trial which is scheduled to begin in March.

There is a fundamental question of statutory interpretation at issue here that merits the extraordinary remedy of an interlocutory appeal: Can a term in a statute that an industry has used for more than 35 years be interpreted in a way that the industry would not have understood? We respectfully submit that basic principles of due process and fundamental fairness dictate that the answer to that question is no. Even if the meaning of an industry term is "unsettled" in some sense (and we do not agree that it is), we believe it was error for the Court to interpret the term "average wholesale price" in a way that was contrary to the industry's understanding.

Conclusion

For the forgoing reasons, the Court should grant BMS's motion for reconsideration or, in the alternative, certify pursuant to 28 U.S.C. § 1292(b) the controlling question of the proper interpretation of Section 4556(a) of the Balanced Budget Act of 1997, because the legislative history of that statute and the trade custom and usage surrounding the term used therein presents substantial ground for difference of opinion and because the interpretation of the statute presents a controlling question of law the resolution of which would materially advance the termination of this litigation.

Dated: Boston, Massachusetts
November 17, 2006

Respectfully Submitted,

By: /s/ Jacob T. Elberg

Thomas E. Dwyer (BBO No. 139660)
Jacob T. Elberg (BBO No. 657469)
DWYER & COLLORA, LLP
600 Atlantic Avenue
Boston, MA 02210
Tel: (617) 371-1000
Fax: (617) 371-1037
tdwyer@dwyercollora.com
jelberg@dwyercollora.com

Steven M. Edwards (SE 2773)
Lyndon M. Tretter ((LT 4031)
Admitted *pro hac vice*
HOGAN & HARTSON LLP
875 Third Avenue
New York, NY 10022
Tel: (212) 918- 3640

Attorneys for Defendant Bristol-Myers Squibb Company, Oncology Therapeutics Network, Corp. and Apothecon, Inc.